

1 Jon M. Sands
2 Federal Public Defender
3 District of Arizona
4 Jennifer M. Moreno (CA Bar No. 244967)
5 Therese M. Day (GA Bar No. 213810)
6 Amanda C. Bass (AL Bar No. 1008H16R)
7 Assistant Federal Public Defenders
8 850 West Adams Street, Suite 201
9 Phoenix, Arizona 85007
10 jennifer_moreno@fd.org
11 therese_day@fd.org
12 amanda_bass@fd.org
13 602.382.2718 Telephone
14 602.382.2800 Facsimile
15
16 *Counsel for Plaintiff*

17 **IN THE UNITED STATES DISTRICT COURT**
18 **FOR THE DISTRICT OF ARIZONA**

19 Clarence Wayne Dixon,

20 No. CV-22-00743-PHX-DJH (JFM)

21 Plaintiff,

22 DEATH-PENALTY CASE

23 vs.

24 The Arizona Department of Corrections,
25 Rehabilitation & Reentry (ADCRR);
26 David Shinn, Director of the Arizona
27 Department of Corrections, Rehabilitation
28 & Reentry; James Kimble, Warden, ASPC
– Eyman,

Amended Complaint for Equitable,
Injunctive and Declaratory Relief [42
U.S.C. § 1983]

Defendants.

I. Nature of Action

1. Plaintiff Clarence Wayne Dixon brings this action pursuant to 42 U.S.C. § 1983
for violations by the Arizona Department of Corrections, Rehabilitation and Reentry
("ADCRR") of Plaintiff's Fourteenth Amendment right to due process in the liberty
interest that Defendants have created, and his Eighth Amendment right to be free from
cruel and unusual punishment. U.S. Const. amend XIV, VIII.

1 2. Plaintiff is scheduled to be executed on May 11, 2022, by lethal injection, and
2 alleges that ADCRR intends to carry out his execution using compounded pentobarbital
3 that is expired, which will cause him to suffer an unconstitutional execution.

4 3. The written execution procedures issued by ADCRR prohibit the department from
5 using a drug that has an expiration or beyond-use date (“BUD”) that is after the date an
6 execution is carried out. Ariz. Dep’t of Corr., Rehab. & Reentry, Dep’t Order 710—
7 Execution Procedures, Attachment D at 2 (April 20, 2022),
8 https://corrections.az.gov/sites/default/files/policies/700/0710_031021.pdf (“DO 710”).

9 4. In April 2021, Arizona initiated execution warrant proceedings for Plaintiff, and
10 informed him that the State intended to use compounded pentobarbital and claimed the
11 drug would have a 90-day BUD from the date of compounding. Motion to Set Briefing
12 Schedule for Motion for Warrant of Execution, *State of Arizona v. Clarence Wayne Dixon*,
13 No. CR-08-0025-AP (Ariz. April 6, 2021). However, subsequently, the State admitted that
14 the pharmacist retained to compound the drugs “revised that opinion and has advised
15 ADCRR that, until certain specialized testing of a sample batch is conducted,” the
16 pentobarbital would only have a 45-day BUD. Motion to Modify Briefing Schedule at 2,
17 *State of Arizona v. Clarence Wayne Dixon*, No. CR-08-0025-AP (Ariz. June 22, 2021).
18 The State explained that unless the BUD was extended beyond 45 days, the drugs would
19 be unusable in an execution because the timeline between the initiation of the warrant
20 procedure and the date an execution can be scheduled exceeds 45 days. *Id.* at 2-3.

21 5. In January 2022, the State again initiated warrant proceedings for Plaintiff,
22 claiming that “specialized testing” had been completed and again asserting that the BUD
23 of the drug was at least 90 days from the date of compounding. Motion to Set Briefing
24 Schedule for Motion for Warrant of Execution, *State of Arizona v. Clarence Wayne Dixon*,
25 No. CR-08-0025-AP (Ariz. Jan. 5, 2022). The Arizona Supreme Court issued a warrant
26 of execution for Plaintiff on April 5, 2022. Warrant of Execution, *State of Arizona v.*
27 *Clarence Wayne Dixon*, No. CR-08-0025-AP (Ariz. April 5, 2022).

28

1 6. On May 6, 2022, Defendants produced an affidavit from a pharmacist who purports
2 to assign a BUD of August 25, 2022, to the drug intended for use in Plaintiff's execution.
3 (ECF No. 14.1, Not. Beyond Use Date, Ex. 1, doc. page 2, ¶9.) In support, the pharmacist
4 attached several laboratory results.

5 7. As described more fully below, these testing results demonstrate that the drug failed
6 to pass one component of the stability study test and therefore the BUD cannot be
7 extended. This means the pharmacist inappropriately assigned the drug intended for
8 Plaintiff's execution a BUD of 180 days, when the drug is actually already expired due to
9 the failed test.

10 8. ADCRR's decision to use an expired drug to execute Plaintiff violates his due-
11 process liberty interest and his Eighth Amendment right to be free from cruel and unusual
12 punishment.

13 9. Accordingly, Plaintiff seeks (a) a preliminary and permanent injunction preventing
14 ADCRR from executing him with expired compounded pentobarbital, and (b) an order
15 declaring that executing him with expired pentobarbital violates his right to Due Process
16 under the Fourteenth Amendment to the U.S. Constitution and his Eighth Amendment right
17 under the United States Constitution.

18 10. This Complaint does not challenge Plaintiff's underlying capital conviction or
19 sentence of death, nor does it allege that his execution is *per se* unconstitutional.

20 **II. Jurisdiction and venue**

21 11. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 (federal question), 28
22 U.S.C. § 1343 (civil rights violations), 28 U.S.C. § 2201 (declaratory relief), and 28 U.S.C.
23 § 2202 (injunctive relief). Plaintiff invokes this Court's jurisdiction pursuant to Article III
24 of the United States Constitution, the Fourteenth Amendment to the United States
25 Constitution, the Eighth Amendment to the United States Constitution, and 42 U.S.C. §
26 1983.

27
28

1 12. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1331(b). Plaintiff is
2 currently incarcerated at the Arizona State Prison Complex (“ASPC”) Eyman-Browning
3 Unit, 4374 East Butte Avenue, Florence, Arizona, 85132, located in this District.

4 **III. Parties**

5 13. Plaintiff Clarence Wayne Dixon is a United States and Arizona citizen, and
6 member of the sovereign Navajo Nation. Plaintiff is incarcerated at ASPC Eyman-
7 Browning Unit in Florence, Arizona.

8 14. Plaintiff is currently under a warrant of execution and is scheduled to be executed
9 on May 11, 2022, at ASPC—Florence within the State of Arizona and within this District.

10 15. Defendant David Shinn is the Director of ADCRR and is being sued in his official
11 capacity for equitable, injunctive, and declaratory relief. Director Shinn oversees all
12 ADCRR operations and signed the current version of DO 710.

13 16. Defendant James Kimble is the Warden of ASPC Florence where Plaintiff’s
14 execution is scheduled to take place. Under DO 710, the Warden of ASPC Florence serves
15 as the Housing Unit 9 Section Leader and is responsible for verifying that ADCRR “will
16 only use chemicals in an execution that have an expiration or beyond-use date that is after
17 the date that an execution is carried out.” DO 710 § 3.2.2.3; Attachment D at 1.

18 17. Defendants John Does, Unknown ADCRR Personnel, are staff or agents of
19 ADCRR or the State of Arizona who are ADCRR’s officers, successors in office, agents,
20 contractors, and employees, along with those acting in concert with them, who have
21 participated or will participate in Plaintiff’s execution with an expired execution drug.
22 Plaintiff is not aware of the true identities of John Does, but alleges that when Plaintiff
23 discovers their identities, Plaintiff will amend this Complaint accordingly.

24 **IV. Exhaustion of Administrative Remedies**

25 18. Plaintiff does not believe that exhaustion is necessary under the Prison Litigation
26 Reform Act (“PLRA”), 42 U.S.C. § 1997e, because this suit does not challenge prison
27 conditions and because there are no available administrative remedies that could address
28 the challenged constitutional violation.

1 19. As described more fully below, Plaintiff, through his counsel, has diligently
2 pursued information regarding the compounded drug intended for use in his execution,
3 specifically the BUD and specialized testing on which it is established.

4 20. Only by order of this Court (Order, ECF 12, May 6, 2022), did Defendants produce
5 the information establishing that they intend to carry out his execution with expired
6 pentobarbital (Not., ECF 14, 14.1).

7 **V. Factual Background**

8 21. Plaintiff was convicted and sentenced to death by the State of Arizona in 2008.
9 *State v. Dixon*, 226 Ariz. 545, 548 ¶ 1, 250 P.3d 1174, 1177 (2011).

10 22. On April 5, 2022, the Arizona Supreme Court issued a Warrant of Execution,
11 setting the execution date for May 11, 2022. Warrant of Execution, *State of Arizona v.*
12 *Clarence Wayne Dixon*, No. CR-08-0025-AP (Ariz. April 5, 2022).

13 1. Arizona's Execution Statute and Execution Protocol

14 23. Arizona Revised Statute § 13-757(A) provides that “[t]he penalty of death shall be
15 inflicted by an intravenous injection of a substance or substances in a lethal quantity
16 sufficient to cause death, under the supervision of the state department of corrections.”
17 Additionally, a prisoner like Plaintiff, who was “sentenced to death for an offense
18 committed before November 23, 1992, shall choose either lethal injection or lethal gas at
19 least twenty days before the execution date. If the defendant fails to choose either lethal
20 injection or lethal gas, the penalty of death shall be inflicted by lethal injection.” Ariz.
21 Rev. Stat. § 13-757(B). Plaintiff declined to elect a method of execution and his execution
22 will be carried out by lethal injection.

23 24. ADCRR establishes the written procedures for carrying out executions by lethal
24 injection in DO 710. The current version of DO 710 became effective on April 20, 2022.

25 *See* DO 710.

26 25. DO 710 provides that ADCRR can carry out executions with a drug protocol of
27 five grams of either sodium pentothal (thiopental) or pentobarbital and the Director has

1 the sole discretion to determine which protocol to use. DO 710, Attachment D at 2-3. DO
2 710 also provides that ADCRR can use a compounded version of the drug. *Id.*

3 26. DO 710 prohibits ADCRR from using a drug that is past the expiration date or
4 BUD to carry out an execution. *Id.* at 1.

5 27. DO 710 provides no information and requirements for how the pentobarbital
6 Defendants intend for use in Plaintiff's execution has been or will be compounded,
7 including no requirement that the drug is properly compounded in accordance with
8 applicable standards and best practices and by a qualified and licensed pharmacist.

9 28. The protocol is silent regarding the criteria for determining the BUD and what
10 process is required to extend the BUD.

11 29. DO 710 requires the State to provide notice to the prisoner whether a compounded
12 or non-compounded drug will be used at the time the State files a request for a Warrant of
13 Execution. The State must also provide the prisoner a "quantitative analysis of any
14 compounded or non-compounded chemical to be used in the execution shall be provided
15 upon request within ten calendar days after the state seeks a Warrant of Execution." *Id.* at
16 2.

17 2. The State located a source of compounded pentobarbital and initiated the
18 process of seeking Plaintiff's execution warrant in the Arizona Supreme
19 Court

20 30. In early March 2021, a media article reported that the State had obtained
21 pentobarbital for use in executions. Jacques Billeaud, Arizona finds death penalty drug
22 after hiatus in executions, The Associated Press, Mar. 5, 2021 (available at
23 <https://apnews.com/article/arizona-phoenix-executions-6f0ce846e174119635509e0c16b9ac1d>).

24 31. The next month, on April 6, 2021, the State sought a briefing schedule from the
25 Arizona Supreme Court for its anticipated motion for a warrant for Plaintiff's execution.
26 Motion to Set Briefing Schedule for Motion for Warrant of Execution, *State of Arizona v.*
27 *Clarence Wayne Dixon*, No. CR-08-0025-AP (Ariz. Apr. 6, 2021). In this motion, the
28

1 State claimed—without any support—that the drug to be used in Plaintiff’s execution
2 would have a 90-day BUD. *Id.* at 2.

3 32. On June 22, 2021, the State requested modification of the briefing schedule because
4 its compounding pharmacist had revised the information about the BUD of the
5 compounded pentobarbital. Motion to Modify Briefing Schedule, *State of Arizona v.*
6 *Clarence Wayne Dixon*, No. CR-08-0025-AP (Ariz. June 22, 2021). Whereas the State
7 originally claimed that “based on current testing” by its compounder “the drug has a
8 beyond-use date (aka expiration date) of 90 days from the date of compounding” (2021
9 Mot. to Set Briefing Schedule at 2), the actual shelf life of the compounded drug had a
10 drastically shorter shelf life of only 45 days (see Mot. to Modify Briefing Schedule at 2).
11 The State explained that unless the specialized testing extended the BUD beyond 45 days,
12 the drug would be unusable in an execution because the timeline between the initiation of
13 the warrant procedure and the date an execution can be scheduled exceeds 45 days. *Id.* at
14 2-3.

15 33. On July 12, 2021, the Arizona Supreme Court denied the State’s motion to modify
16 the warrant briefing schedule and ordered that “[t]he State may renew its scheduling
17 motion after specialized testing to determine a beyond-use date for compounded doses of
18 the drug.” Order, *State of Arizona v. Clarence Wayne Dixon*, No. CR-08-0025-AP (Ariz.
19 July 12, 2021).

20 34. On January 5, 2022, the State again initiated warrant proceedings for Plaintiff and
21 filed a motion with the Arizona Supreme Court seeking a briefing schedule for the motion
22 for a warrant of execution. The State claimed that “specialized testing” had been
23 completed and again asserted—again without evidence—that the BUD of the drug was at
24 least 90 days from the date of compounding. Motion to Set Briefing Schedule for Motion
25 for Warrant of Execution at 2, *State of Arizona v. Clarence Wayne Dixon*, No. CR-08-
26 0025-AP (Ariz. Jan. 5, 2022).

27 35. The supreme court set a briefing schedule and, in accordance with that schedule,
28 the State filed a motion for warrant of execution on February 24, 2022. Motion for Warrant

1 of Execution, *State of Arizona v. Clarence Wayne Dixon*, No. CR-08-0025-AP (Ariz. Feb.
2 24, 2022).

3 36. At this time, the State informed Plaintiff that compounded pentobarbital would be
4 used to carry out his execution. Letter, Sparks to Plaintiff's Counsel, Feb. 24, 2022.

5 37. On February 25, 2022, under Department Order 710, Attachment D, counsel for
6 Plaintiff requested that the State produce within ten calendar days a quantitative analysis
7 of the compounded pentobarbital the State intends to use if an execution date were
8 scheduled for Plaintiff.

9 38. On March 4, 2022, the State produced a heavily redacted single page test result that
10 is not a quantitative analysis (Expert Report of Michaela Almgren, PharmD, MA, March
11 10, 2022 ("Almgren Report") ¶ 14 (Ex. 1)), and indicates only that the substance contains
12 pentobarbital.

13 39. That document does not provide a BUD for the drug.

14 40. In response to the very limited information released, counsel for Plaintiff requested
15 that the State produce all documents related to the specialized testing of its compounded
16 pentobarbital, including all documents related to the BUD. Email Bass to Sparks, Mar. 4.
17 2022.

18 41. On March 15, 2022, the State produced three heavily redacted pages of lab reports
19 from an unidentified batch or batches of compounded pentobarbital. These test results did
20 not identify when the drug or drugs were compounded, what significance the tests had to
21 the drugs intended for use in Mr. Dixon's execution, and did not provide an assigned BUD.

22 42. On April 5, 2022, the Arizona Supreme Court issued a warrant of execution for
23 Plaintiff and set his execution for May 11, 2022. Warrant of Execution, *State of Arizona*
24 *v. Clarence Wayne Dixon*, No. CR-08-0025-AP (Ariz. April 5, 2022).

25 43. On April 14, 2022, the State produced four additional pages of redacted laboratory
26 test results responsive to Plaintiff's counsel's March 4, 2022 request. The results did not
27 identify whether the analysis was performed on the drug intended for use in Plaintiff's
28 execution or some other batch of pentobarbital. The test results provided data regarding

1 sterility, pH, and drug potency, but did not identify the date of compounding and did not
2 provide an assigned BUD.

3. Plaintiff diligently sought information about the BUD assigned to the
compounded pentobarbital intended for use in his execution

44. Since the State of Arizona announced in March 2021 that it had identified a source
6 of pentobarbital, Plaintiff, through counsel, diligently sought information about the State's
7 supply of pentobarbital, including the assignment of the drug's BUD and supporting
8 scientific documentation.

45. On March 8, 2021, the Office of the Federal Public Defender, Capital Habeas Unit
10 ("FPD"), sent a letter to Director Shinn seeking information about Defendants' supply of
11 pentobarbital. Letter, Baich to Shinn, Mar. 8, 2021.

46. On May 13, 2021, ADCRR produced some records responsive to the FPD's
13 request, including execution training documents, documents related to the refurbishment
14 of the gas chamber, and a \$440,000 invoice for "pharmaceutical consultation services."
15 ADCRR did not produce any information regarding the expiration date or BUD related to
16 the supply of pentobarbital.

47. On July 21, 2021, after the supreme court denied the State's motion to modify the
18 briefing schedule, counsel for Plaintiff requested information from Defendants regarding
19 the supply of pentobarbital, including the "specialized testing" referenced in the State's
20 June 2, 2021, Motion to Modify Briefing Schedule and documents, laboratory results,
21 testing standards, timelines, and protocols related to the BUD, specifically the extension
22 of the BUD beyond 45 days. Letter, Baich to ADCRR Public Information Officer, Jul. 21,
23 2021.

48. In response to this request, the State produced a combination of previously
25 produced documents and new documents. The release included heavily redacted drug
26 purchase documents, execution training materials, and two lab reports indicating only that
27 the substance tested contained pentobarbital. None of the documents provide any
28

1 information about the BUD of the compounded pentobarbital or the testing protocols
2 Defendants' pharmacist would use or rely on to set and extend the BUD beyond 45 days.

3 49. As discussed above, on February 25, 2022, after the State filed the Motion for a
4 Warrant of Execution, Plaintiff requested that the State produce a quantitative analysis of
5 the compounded pentobarbital as set forth in DO 710.

6 50. The State produced a single heavily redacted page that did not include any BUD-
7 related information.

8 51. On March 4, 2022, as discussed above, Plaintiff's counsel requested additional
9 information about the "specialized testing" relied on by the State to extend the BUD.

10 52. On March 15, 2022, the State produced three additional, heavily redacted pages
11 that did not include any BUD-related information.

12 53. On April 14, 2022, counsel for Plaintiff, again emailed counsel for Defendants, and
13 specifically asked for documentation regarding the BUD assigned to the compounded
14 pentobarbital intended for use in Plaintiff's execution. Email, Bass to Sparks, April 14,
15 2022.

16 54. On April 22, 2022, Sarah Greener, ADCRR's Attorney General Liaison, responded
17 by telephone that she was working on producing documents responsive to the request for
18 BUD information and anticipated providing that information to Plaintiff sometime in the
19 next week.

20 55. As of May 2, 2022, the State has not produced any documentation or supporting
21 scientific data for the BUD assigned to the compounded pentobarbital intended for use in
22 Plaintiff's execution.

23 56. On May 6, 2022, Defendants produced an affidavit from a pharmacist that asserts
24 the compounded drug has a BUD of August 25, 2022 (Not. Beyond Use Date, ECF 14.1,
25 Ex. 1, doc. page 2, ¶ 8), which is 180 days after the pharmacist compounded the drug.

26 57. The pharmacist states that she or he provided a solution of pentobarbital to "a FDA
27 registered laboratory for stability testing in order to establish the solution's Beyond Use
28 Date." Not. Beyond Use Date, ECF 14.1, Ex. 1, doc. page 2, ¶ 6.

1 58. The pharmacist states that they prepared the compounded pentobarbital intended
2 for use in Plaintiff's execution on February 26, 2022. (Not. Beyond Use Date, ECF 14.1,
3 Ex. 1, doc. page 2, ¶ 8).

4 59. The pharmacist states that the BUD for the compounded pentobarbital intended for
5 use in Plaintiff's execution is August 25, 2022. (Not. Beyond Use Date, ECF 14.1, Ex. 1,
6 doc. page 2 ¶ 9.)

7 60. The pharmacist states that the BUD is "based on the stability study results[.]" (Not.
8 Beyond Use Date, ECF 14.1, Ex. 1, doc. page 2 ¶ 9.)

9 61. The testing of the unidentified compounded pentobarbital reflects a pH of 10.6.
10 (Not. Beyond Use Date, ECF 14.1, Attach. 2, doc. page 9.)

11 62. The pharmacist asserts that she or he is "aware of and follow[s] the guidelines and
12 requirements found in the United States Pharmacopeia." (Not. Beyond Use Date, ECF
13 14.1, Ex. 1, doc. page 2, ¶ 3); *see also* Almgren Rep. ¶ 9 ("A compounding pharmacist
14 should be very familiar with USP 797 guidelines in order to prepare safe and effective
15 sterile compounded products.").

16 63. The laboratory's "Project Summary and Results" of the unidentified compounded
17 pentobarbital indicates that the tests were based on "client provided specifications[.]"
18 (Not. Beyond Use Date, ECF 14.1, Attach. 2, doc. page 13.)

19 64. The testing on which the pharmacist based the BUD was completed one month
20 after the pharmacist compounded the drug intended for use in Plaintiff's execution. (Not.
21 Beyond Use Date, ECF 14.1, Attach. 2, doc. pages 8, 9, 10, 13 (defining test time as "Day
22 180").)

23 65. In January 2022, at the time the State informed the Arizona Supreme Court that
24 "specialized testing" had been completed, and asserted that the BUD of the drug was at
25 least 90 days from the date of compounding (Motion to Set Briefing Schedule for Motion
26 for Warrant of Execution, *State of Arizona v. Clarence Wayne Dixon*, No. CR-08-0025-
27 AP (Ariz. Jan. 5, 2022)), the stability study had not yet been completed. (Not. Beyond
28 Use Date, ECF 14.1, Attach. 3., doc. page 3.)

1 66. Due to Plaintiff's advanced age and declining health, he is at an increased risk that
 2 subpotent or otherwise compromised drugs will increase the chance that he experiences
 3 pain and suffering during his execution. This is because his "heart, lungs and liver all show
 4 damage that likely will alter the way the [execution] drug is both delivered and
 5 metabolized." Declaration of Tara Cuccinelli, April 21, 2022 at 3 (Ex. 3). "His lungs, liver
 6 and heart are damaged enough that it might take longer to circulate the medication to reach
 7 full toxicity dose leaving him feeling some of the effects of Pentobarbital but not all of
 8 them." *Id.* at 3.

9 4. Requirements for compounded drugs

10 67. Pharmacy compounding is a practice in which a licensed pharmacist combines,
 11 mixes, or alters ingredients of a drug to create a medication that is tailored to the specific
 12 medical needs of a patient. "Human Drug Compounding," U.S. Food & Drug
 13 Administration, <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding> (last visited Apr. 30, 2022).

15 68. In general pharmacy compounding, drugs can only be compounded upon the
 16 receipt of a valid patient-specific prescription, among other requirements. "Compounding
 17 Laws and Policies," U.S. Food and Drug Administration,
 18 <https://www.fda.gov/drugs/human-drug-compounding/compounding-laws-and-policies>
 19 (last visited Apr. 30, 2022).

20 69. Compounded drugs are not approved by the Food and Drug Administration (FDA)
 21 and are subject to less rigorous regulation and oversight relating to the identity, purity,
 22 and potency of the drug than are manufactured drugs. *See id.*

23 70. The process of compounding drugs must meet the requirements contained in the
 24 United States Pharmacopeia (USP). *See Almgren Report ¶ 9.*

25 71. The USP is a compendium of quality requirements, quality specifications,
 26 practices, and guidelines to achieve the highest pharmaceutical quality for pharmacy
 27 practice as well as the pharmaceutical industry. *See Almgren Report ¶ 9.*

28 USP Chapters 1 through 999 are enforceable by the FDA. *Almgren Report ¶ 9.*

1 72. According to the USP, medications intended for intravenous injection are required
2 to be sterile. *See* USP, General Chapter <797> available at
3 <https://www.usp.org/compounding/general-chapter-797> (last visited Apr. 30, 2022).

4 73. Sterile injectables must be compounded under aseptic conditions and in accordance
5 with best practices to maintain sterility and a compounding environment free from
6 contamination. *See* Almgren Report ¶ 8.

7 74. Compounded drugs are prepared using Active Pharmaceutical Ingredients (API),
8 which are not typically sterile, which requires drug sterility testing to ensure the drug is
9 not contaminated. *See* Almgren Report ¶ 12.

10 75. Compounded drugs have an expiry date known as a “beyond use date” (BUD),
11 which is significantly shorter than the expiration date for commercially available products
12 because compounded drugs do not undergo the same extensive quality testing. *See*
13 Almgren Report ¶ 10.

14 76. BUDs are established by USP. According to USP, the maximum BUD for
15 compounded sterile preparations like compounded pentobarbital are:

- 16 • 24 hours, if stored at room temperature;
- 17 • 72 hours, if kept refrigerated; or
- 18 • 45 days, if kept in a solid, frozen state.

19 Almgren Report ¶ 10.

20 77. BUDs must be assigned by the compounder and must appear on the label. USP,
21 General Chapter <797> Pharmaceutical Compounding—Sterile Preparations (“USP
22 <797>”), at “Identity and Strength Verification of Ingredients”

23 78. Stability studies must be performed in order to extend the expiry for compounded
24 drugs beyond the BUD established by the USP. *See* Almgren Report ¶ 11. Guidelines for
25 performing adequate stability studies are set forth in FDA guidance documents. The
26 guidelines typically require testing multiple samples stored under specified conditions and
27 tested at regular intervals to determine if changes to the drug quality occurs, which would
28

1 signal that a drug expired, and the pharmacological action cannot be guaranteed. *See id.* ¶

2 11.

3 79. Stability studies are carefully designed to assure the drug maintains integrity and
4 pharmacological properties over time. *See* Supplemental Report of Michaela Almgren,
5 PharmaD, MA, March 31, 2022 (“Almgren Suppl. Report”) ¶ 6 (Ex. 2). Stability study
6 design must be specified in a test protocol that applies to the specific compounding
7 process, formulation or recipe, container closures system, storage conditions, and batch
8 size. *See id.* ¶ 7. A new stability study must be performed if any of these factors change
9 between batches. *See id.*

10 80. Stability studies are also typically performed by testing multiple samples of a
11 compounded drug from at a minimum of three different batches. Almgren Suppl. Report
12 ¶ 8.

13 81. Stability study tests are also performed at specific timing intervals, for example at
14 the point the drug is compounded and then monthly, to establish an understanding of the
15 drug’s degradation process over time. Almgren Suppl. Report ¶ 11.

16 82. Once compounded, sterile injectables must be stored under proper conditions,
17 defined by the USP or a stability study, or the drugs can become damaged, unusable, and
18 unsafe leading to unpredictable results and pain and suffering. Almgren Report ¶ 21.

19 83. Compounding of sterile injectable pentobarbital is a complex and highly
20 specialized process that requires specialized equipment, numerous pharmaceutical-grade
21 ingredients, chemical adjustments during the process, and, of course, the appropriate
22 experience and credentials in aseptic compounding technique. *See* Almgren Report ¶¶ 26-
23 27.

24 84. Even minor deviations from the complex procedures for compounding
25 pentobarbital can impact the safety and efficacy of the drug including resulting in
26 insufficient potency. *See* Almgren Report ¶ 28. “If USP Chapter 797 guidance is not
27 followed it can lead to medication contamination which will cause patient harm and
28 unpredictable drug effects.” Almgren Rep. ¶ 9.

1 85. For these reasons, there is a substantial risk that compounded drugs generally, and
2 pentobarbital specifically, will be contaminated, handled improperly, or suffer from
3 quality issues, the most common and concerning of which is lack of potency.

4 86. These risks increase if the drug is used past the assigned BUD. Expired drugs can
5 have unpredictable pharmacological effects due to loss of potency and degradation. *See*
6 Almgren Report ¶ 5.

7 87. The use of contaminated, impure, or sub-potent compounded pentobarbital “creates
8 the risk that these drugs will not be sufficiently effective and will not have the necessary
9 pharmacological effect.” Almgren Report ¶ 35.

10 The USP monograph for compounded pentobarbital include a pH value of “between 9.0
11 and 10.5.” (Emergency Mot. TRO or Prelim. Inj. and Mem. in Support, at Ex. 1, ECF 5.1.)

12 88. Determining the pH value in compounded pentobarbital is “important[,]” Almgren
13 Supplemental Rep. ¶ 17; “the pH is crucial because the wrong pH can result in formation
14 of precipitant, leading to reduction or loss of pharmacological activity of the drug. It can
15 also cause tissue irritation and damage, causing severe pain when infused.” Almgren
16 Supplemental Rep. ¶ 17

17 5. Issues with ADCRR’s compounded pentobarbital

18 89. Arizona intends to use an intravenous injection of compounded pentobarbital to
19 execute Plaintiff.

20 90. The compounded pentobarbital is a sterile injectable, which must have a properly
21 determined BUD. USP <797> at “Storage and Beyond-Use Dating.”

22 91. The sterile injectable must be labeled with the BUD. USP <797> at “Identity and
23 Strength Verification of Ingredients.”

24 92. The limited test results produced by the State are inadequate to assign a BUD to
25 the compounded pentobarbital, let alone extend a sterile injectable beyond 45 days, both
26 because one of the values fails to meet the USP monograph for compounded pentobarbital
27 (Not. Beyond Use Date, ECF 14.1, Attach. 2, doc. pages 9, 13), and because the limited
28

1 nature of the information does not provide the other required information needed to
 2 determine a drug's expiration date. *See* Almgren Suppl. Report ¶ 5.

3 93. The limited test results lack many basic elements of typical stability study for
 4 compounded sterile injectables, including information about the study design and
 5 parameters; the examination of multiple samples from multiple batches; the specific
 6 compounding recipe used to prepare the compound; and the timing intervals for the tests.
 7 *See* Almgren Suppl. Report ¶¶ 6-11.

8 94. The limited test results fail to include data regarding the API and whether it
 9 contained any impurities that can affect the pharmacology of the finished product.
 10 Almgren Suppl. Report ¶ 22.

11 95. The limited test results include a value for the pH that fails to meet the USP
 12 monograph for compounded pentobarbital. *Compare* USP monograph for compounded
 13 pentobarbital ("pH [USP] <791>: between 9.0 and 10.5.") with Not. Beyond Use Date,
 14 ECF 14.1, Attach. 2, doc. pages 9, 13 (indicating that method for determining pH was
 15 USP <791> and providing value of 10.6 at 180 days).

16 6 Arizona intends to execute Plaintiff with an expired drug.

17 96. Defendants have provided results of stability testing that demonstrate that the
 18 compounded drug failed one of the USP monograph values, which was part of the "client
 19 provided specifications" (Not. Beyond Use Date, ECF 14.1, Attach. 2, doc. page 13).

20 97. During oral argument on May 7, 2022, counsel for Defendants erroneously stated
 21 that the test value relating to the pH value is not a necessary aspect of determining a BUD.
 22 (Hr'g Tr. May 7, 2022, at 11.)

23 98. Defendants intend to carry out Plaintiff's May 11, 2022, execution with a drug that
 24 is expired. The use of expired execution drugs violates the express provisions of DO 710.
 25 DO 710, Attach. D at A.1.III.

26 99. The use of a drug that does not have the proper pH can cause Plaintiff to experience
 27 "extreme pain" and suffering during the execution. Almgren Rep. ¶ 28; Almgren
 28 Supplemental Rep. ¶ 14 (explaining that a precipitate can form "most often due to changes

1 in temperature or the pH of the solution. This can be a serious quality concern, as injection
2 of a solution containing particles may lead to directly causing severe tissue injury and
3 thromboembolism, which can be extremely painful.”).

4 100. Defendants have a feasible, readily available alternative: they can comply with
5 their own written protocol and use a drug that will not be expired on the date of his
6 execution.

7 101. That this alternative is “feasible” is demonstrated by Defendants’ own execution
8 protocol, which requires that the Housing Unit 9 Section Leader “*shall... [e]nsure* that
9 complete sets of chemicals are on site, *not expired*, and immediately available for use.”
10 DO 710, Att. D at A.1.III (emphasis added). *See* DO 710, Att. D at 1.

11 102. That this alternative is readily available is demonstrated Defendants’ actions in this
12 case. Defendants have retained a compounding pharmacist to make the drug and an FDA
13 registered laboratory that can perform the requisite testing.

14 **Claim One: Defendants’ decision to use an expired compounded drug in his
15 execution denies Plaintiff his federal rights to due process under the Fourteenth
16 Amendment.**

17 103. Plaintiff incorporates by reference every statement and allegation set forth
18 throughout this Complaint as if fully rewritten.

19 104. The Fourteenth Amendment prohibits a state from depriving “any person of life,
20 liberty, or property, without due process of law[.]” U.S. Const. amend XIV.

21 105. Plaintiff has a liberty interest in assuring that his execution is carried out in a
22 manner consistent with the requirements of the execution protocol, DO 710 and the
23 Fourteenth Amendment.

24 106. Because Defendants deliberately choose to ignore data from the studies that their
25 pharmacist commissioned, they will use an expired drug in Plaintiff’s execution.

26 107. Defendants’ use of an expired drug in Plaintiff’s execution violates Defendants’
27 written execution protocol, DO 710. Therefore, Defendants’ actions will violate Plaintiff’s
28 liberty interest that is guaranteed by the due-process clause of the Fourteenth Amendment.

1 **Claim Two: Defendants' intention to use an expired compounded drug in his**
2 **execution violates Plaintiff's Eighth Amendment right to be free from cruel and**
3 **unusual punishment.**

4 108. Plaintiff incorporates by reference every statement and allegation set forth
5 throughout this Complaint as if fully rewritten.

6 109. The Eighth Amendment forbids the government from inflicting pain beyond that
7 necessary to end the condemned prisoner's life, when it carries out a death sentence. *In re*
8 *Kemmler*, 136 U.S. 436, 447 (1890). "Punishments are cruel when they involve torture or
9 a lingering death . . . something more than the mere extinguishment of life." *Id.* A method
10 of execution violates the Eight Amendment if it presents a "substantial risk of serious
11 harm." *Baze v. Rees*, 553 U.S. 35, 50 (2008).

12 110. The use of an expired execution drug presents a substantial risk of serious harm
13 due to the risk of, *inter alia*, out-of-range pH values that can lead to thromboembolism,
14 tissue damage, and other extreme pain; unpredictable pharmacological activity; sub-
15 potency; and degradation among other problems. *See, e.g.*, Almgren Supplemental Rep.
16 at ¶¶ 17, 20; Almgren Rep. at ¶ 34.

17 Plaintiff suffers from multiple circulatory and liver conditions that can alter the way the
18 drugs are delivered and circulate through his system, such that it will take longer for the
19 drug to take full effect.

20 111. The use of a subpotent drug on a person with circulatory and hepatic conditions
21 will require a longer time reach full effect, which puts Plaintiff at grave risk of a "lingering
22 death." *Kemmler*, 136 U.S. at 447.

23 112. Plaintiff must also plead identify an alternative that is "feasible, readily
24 implemented, and in fact significantly reduce[s] a substantial risk of severe pain." *Glossip*
25 *v. Gross*, 576 U.S. 863, 877 (2015) (internal quotation omitted).

26 113. Defendants have a known and available alternative—that they use a drug that will
27 not be expired on the date of his execution.

1 114. The alternative is known—Defendants’ own execution protocol requires this
2 alternative: The Housing Unit 9 Section Leader “*shall... [e]nsure* that complete sets of
3 chemicals are on site, *not expired*, and immediately available for use.” DO 710, Att. D at
4 A.1.III (emphasis added).

5 115. The alternative is available: Defendants have retained a compounding pharmacist
6 to make the drug, and an FDA-registered laboratory that can perform the requisite testing.
7 Defendants have already availed themselves of these steps.

8 116. Using a drug that is not expired, and that therefore has guarantees of potency,
9 sterility, appropriate pH, and other factors, will significantly reduce the risk that a
10 compromised drug will cause an “objectively intolerable risk of harm.” *Glossip*, 576 U.S.
11 at 877 (internal quotations omitted).

12 **Prayer For Relief**

13 WHEREFORE, Plaintiff prays for:

14 1. Temporary, preliminary, and permanent injunctive relief to enjoin the Defendants,
15 their officers, agents, servants, employees, and all persons from executing Plaintiff until
16 Defendants have a non-expired source of compounded pentobarbital that has been
17 assigned a scientifically supportable BUD or expiration date beyond the date of his
18 scheduled execution, in order to ensure that his execution is carried out in a manner that
19 does not violate his due process rights under the Fourteenth Amendment, and his right to
20 be free from cruel and unusual punishment under the Eighth Amendment.

21 2. Appropriate and necessary discovery and an evidentiary hearing to permit Plaintiff
22 to prove his constitutional claims; and

23 3. Any such other relief as this Court deems just and proper.

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Respectfully submitted this 8th day of May, 2022.

Jon M. Sands
Federal Public Defender
District of Arizona

Jennifer M. Moreno
Therese M. Day
Amanda C. Bass
Assistant Federal Public Defenders

s/ Jennifer M. Moreno
Counsel for Plaintiff

Certificate of Service

I hereby certify that on May 8, 2022, I electronically filed the foregoing Amended Complaint for Equitable, Injunctive and Declaratory Relief [42 U.S.C. § 1983] with the Clerk's Office using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

s/ Kat Esparza

Assistant Paralegal Capital Habeas Unit